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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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HEDMAN & COSTIGAN P.C.
1185 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER	
CHOJNACKI, MELLISSA M	
ART UNIT	PAPER NUMBER
2164	

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/016,868	SEELINGER, PAUL	
	Examiner	Art Unit	
	Mellissa M. Chojnacki	2164	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5 and 7-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5 and 7-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

SAM RIMELL
PRIMARY EXAMINER

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02-June-2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Remarks

1. In response to communications filed on September 16, 2005, no claims are cancelled; no claims have been amended, and no new claims have been added. Therefore, claims 1, 3-5 and 7-18 are still presently pending in the application.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Mayaud (U.S. Patent No. 5,845,255).

As to claim 14, Mayaud teaches a method of creating and using product recall information, the method comprising the steps of:

a. accessing product recall information for manufactured products (See abstract; column 1, lines 12-19; column 33, lines 29-34);

b. creating at least one product recall database (See abstract; column 5, lines 44-48; column 47, lines 47-53; column 33, lines 29-34);

c. updating product recall data in real time (See column 5, lines 44-48; column 14, lines 66-67; column 15, lines 1-6; column 33, lines 29-34); and

d. disseminating product recall information in real time or on a designated schedule via the Internet to institutionally-based local data repositories to support and

use medication safety systems at healthcare institutions (See column 5, lines 44-48; column 14, lines 66-67; column 15, lines 1-6; column 33, lines 29-34);

e. accessing product data information at the time of administering institutionally dispensed medication, combinations of medications, and/or patient-specific prepared medications by an authorized person to an institutionally based patient (See abstract; (See column 1, lines 46-52; column 2, lines 65-67; column 3, lines 1-19; column 4, lines 22-43; column 5, lines 5-32, lines 45-48; column 30, lines 11-24; column 47, lines 47-53).

As to claim 15, Mayaud teaches wherein the at least one product recall database additionally stores previously known product recall data associated with the product (See Mayaud, abstract; column 5, lines 44-48; column 47, lines 47-53; column 33, lines 29-34).

As to claim 16, Mayaud teaches further comprising means for receiving and storing messages relating to product recalls, the messages being automatically displayed to a user upon the identification of the user (See Mayaud, column 23, lines 19-39; column 33, lines 29-34).

As to claim 17, Mayaud teaches further comprising means for receiving and storing messages relating to product recalls, the messages consisting of data comprising at least one of the items selected from the following: identification of the

product, lot numbers recalled, reasons for recall, and severity of recall (See Mayaud, column 23, lines 19-39; column 33, lines 29-34).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1,3-5, 7-13 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayaud (U.S. Patent No. 5,845,255) in view of Lester et al., (U.S. Patent No. 6,021,392).

As to claim 1, Mayaud teaches a secure, Internet-based universal data repository system for medical product information (See column 48, lines 52-60, where "repository" is read on "data warehouse"), the system comprising

a) a database for dissemination of information and/or identification of institutionally dispensed medication, combinations of medications (See column 30, lines 11-24), and/or patient-specific prepared medications upon administration by an authorized person to institutional based patients (See column 1, lines 46-52; column 4, lines 22-43; column 5, lines 5-32), containing medical product and administration information for their safe and rational utilization said database being updated on

substantially a real time basis, (See abstract; column 5, lines 5-32, lines 45-48; column 47, lines 47-53) comprising one or more of the following fields or combinations of fields:

i) specially defined and formatted product descriptions, including NDC numbers;

ii) safety codes;

iii) product scan codes (See column 30, lines 11-38, where "scan codes" is read on "bar codes"; column 52, lines 27-32);

iv) product recall information (See column 33, lines 29-34); and

v) product equivalency information (See column 4, lines 56-65)

vi) optionally, company specific product information for specific technology products (See column 53, lines 13-22); and

b) a user access data auditor, which provides a user data access audit trail (See column 15, lines 42-45);

c) a programmed system computer for processing and storing the medical product information (See column 31, lines 39-49);

d) an input device operatively interconnected to the programmed system computer means (See column 7, lines 62-67); and

e) an output device operatively interconnected to the programmed system computer means (See column 55, lines 15-17).

Mayaud does not teach wherein the product scan code(s) includes at least one medication identifier and information comprising at least one of the items selected from the group consisting of NDC number having associated lot/control/batch numbers and

expiration date, GTIN number and UPC Code, and are associated with one or more products and/or patient-specific prepared product and/or medications, combinations, and/or patient-specific prepared medications to be administered to an inpatient.

Lester et al. teaches a system and method for drug management (See abstract), in which he teaches wherein the product scan code(s) includes at least one medication identifier and information comprising at least one of the items selected from the group consisting of NDC number having associated lot/control/batch numbers and expiration date (See abstract; column 2, lines 38-53; column 7, lines 36-54), GTIN number and UPC Code (See column 14, lines 51-65), and are associated with one or more products and/or patient-specific prepared product and/or medications, combinations, and/or patient-specific prepared medications to be administered to an inpatient (See column 1, lines 33-47).

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention was made to have modified Mayaud, to include wherein the product scan code(s) includes at least one medication identifier and information comprising at least one of the items selected from the group consisting of NDC number having associated lot/control/batch numbers and expiration date, GTIN number and UPC Code, and are associated with one or more products and/or patient-specific prepared product and/or medications, combinations, and/or patient-specific prepared medications to be administered to an inpatient.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified Mayaud, by the teachings of Lester et al.

because wherein the product scan code(s) includes at least one medication identifier and information comprising at least one of the items selected from the group consisting of NDC number having associated lot/control/batch numbers and expiration date, GTIN number and UPC Code, and are associated with one or more products and/or patient-specific prepared product and/or medications, combinations, and/or patient-specific prepared medications to be administered to an inpatient would assist a hospital's pharmacist or pharmacy department with maintaining accurate records while attempting to reduce the burden of managing all of the information associated with drug distribution (See Lester et al., column 1, lines 29-33).

As to claim 3, Mayaud as modified, teaches where the user access data auditor strictly controls access to Internet-based data tables by user type and privilege, and wherein the auditor logs when a user views a recall message, thereby tracking whether the recall message has been viewed (See Mayaud, column 15, lines 42-45; column 16, lines 1-5; column 17, lines 60-67; column 18, lines 1-5).

As to claim 4, Mayaud as modified, teaches comprising an updating and maintaining (See Mayaud, column 14, lines 32-37; column 14, lines 66-67; column 15, lines 1-6; lines 20-25) means for the medical product information via Internet communication by accessing a dedicated web site (URL) using web browsers (See Mayaud, column 48, lines 1-7).

As to claim 5, Mayaud as modified, teaches wherein the input and output devices comprise a computer display screen having the medical product information displayed in fields (See Mayaud, column 6, lines 37-57; also see Fig. 1-14).

As to claim 7, Mayaud as modified, teaches further comprising a voice recognition unit for permitting the user to communicate with the system by verbal inputs (See Mayaud, column 9, lines 17-23; column 10, lines 3-8).

As to claim 8, Mayaud as modified, teaches wherein the input device cooperates with the voice recognition unit (See Mayaud, column 9, lines 17-23; column 10, lines 3-8).

As to claim 9, Mayaud as modified, teaches wherein the input means further comprises a pen interface for permitting a user to communicate with the system by writing on a screen with a pen (See Mayaud, column 7, lines 44-56).

As to claim 10, Mayaud as modified, teaches wherein the information is received by at least one output device taken from the group consisting of voice, a keyboard, a pen and a mouse (See Mayaud, column 7, lines 44-56, column 9, lines 17-23; column 10, lines 3-8; column 55, lines 15-17).

As to claim 11, Mayaud, as modified, teaches wherein the medical product is taken from the group consisting of manufactured generic, brand, over-the-counter, biologicals, blood products, medical devices, intravenous solutions, and patient-specific prepared medication comprised of one or more medications (See Mayaud, column 1, lines 46-52; column 4, lines 56-65; column 26, lines 21-25; column 29, lines 47-50; column 48, lines 29-38; column 57, lines 63-67; column 58, lines 1-2).

As to claim 12, Mayaud, teaches a method for creating and using product data (See abstract; column 48, lines 52-60), the method comprising the steps of:

b. creating at least one product identification and description database (See abstract; column 5, lines 44-48; column 47, lines 47-53);

c. updating product specific data in real time (See column 5, lines 44-48; column 14, lines 66-67; column 15, lines 1-6);

d. disseminating product information and recall information in real time or on a designated schedule via the Internet to institutionally-based local data repositories to support and use medication safety systems at healthcare institutions (See column 5, lines 44-48; column 14, lines 66-67; column 15, lines 1-6; column 33, lines 29-34); and

e. accessing product data information at the time of administering institutionally dispensed medication combinations of medications and/or patient-specific prepared medications by an authorized person to an institutionally based patient (See column 1, lines 46-52; column 4, lines 22-43; column 5, lines 5-32, lines 45-48; column 30, lines 11-24; column 47, lines 47-53).

Mayaud does not teach accessing product scan code information for manufactured products.

Lester et al. teaches a system and method for drug management (See abstract), in which he teaches wherein accessing product scan code information for manufactured products (See abstract; column 2, lines 38-53; column 7, lines 36-54; column 14, lines 51-65).

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention was made to have modified Mayaud, to include accessing product scan code information for manufactured products.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified Mayaud, by the teachings of Lester et al. accessing product scan code information for manufactured products would assist a hospital's pharmacist or pharmacy department with maintaining accurate records while attempting to reduce the burden of managing all of the information associated with drug distribution (See Lester et al., column 1, lines 29-33).

As to claim 13, Mayaud as modified, teaches comprising retrieving product information across a network or the Internet from a remote source database and displaying or otherwise using retrieved product information in real time (See Mayaud, column 5, lines 44-48; column 14, lines 66-67; column 15, lines 1-6; column 48, lines 1-7).

As to claim 18, Mayaud as modified, teaches further comprising means operable to use the medical product database and patient specific information to calculate a dosage recommendation, including an amount and a frequency of administration of the medical product (See Mayaud, column 4, lines 30-41; column 5, lines 25-32).

Response to Arguments

6. Applicant's arguments filed on September 14, 2004, with respect to the rejected claims 1-18 have been fully considered but they are not found to be persuasive:

In response to applicants' arguments regarding claim 14, that Mayaud does not teach *"accessing product data information at the time of administering institutionally dispensed medication, combinations of medications, and/or patient-specific prepared medications by an authorized person to an institutionally based patient"*, the arguments have been fully considered but are not found to be persuasive, because Mayaud teaches a multi-patient version of the drug dosage dispenser, which not only can provide inpatient central dispensing station, having multiple ports, preferably identified with bed locations and bed-occupants' names, whereby scheduled drug dosages for each bed-occupant patient are dispensed at scheduled dosage intervals, but also appropriate alerts or indicators which can be interrupted as certain drug information, patient information and/or alerts of a drug recall (See column 31, lines 5-17). Mayaud also discloses physician's approval prior to creating or supplying a patient with the appropriate medication they need and it is at the time that a physician can be informed of any recalls or other important drug information (See column 27, lines 30-35).

Furthermore, Mayaud discloses "interactive screening maybe run on pharmacy-related systems and notification of problems can be sent immediately to the user's point-of-care device" (See column 31, lines 39-49), which shows that product data can be sent immediately to the point-of-care device, which can be within a hospital/medical facility. It is also inherent that hospital/medical facility can have pharmacy's where medication is prepared to be distributed to patients with the hospital/facility or the point-of-care device, which is used by a physician/medical person to receive the prescription in order to distribute it to a patient can be in the actual hospital/medical facility and therefore any "product data" would be seen at that time.

In response to applicants' arguments regarding claims 1, 3-5, 7-13 and 18, that *"Mayaud does not teach or suggest the use of real time product data information by authorized personnel at the time of administration of the medication to an institutionally based patient, as required in Claim 1".* The arguments have been fully considered but are not found to be persuasive, because Mayaud discloses "interactive screening maybe run on pharmacy-related systems and notification of problems can be sent immediately to the user's point-of-care device" (See column 31, lines 39-49), which shows that product data can be sent immediately to the point-of-care device, which can be within a hospital/medical facility. It is also inherent that hospital/medical facility can have pharmacy's where medication is prepared to be distributed to patients with the hospital/facility or the point-of-care device, which is used by a physician/medical person to receive the prescription in order to distribute it to a patient can be in the

actual hospital/medical facility and therefore any "product data" would be seen at that time. Mayaud also discloses that the "prescription management system" consists of a "retrieval and updating system" (See column 32, lines 22-67; column 33, lines 1-52).

In response to applicants' arguments regarding "prima facie case of obviousness...The present case provides no suggestion or motivation (expressed or implied) based on Lester or Mayaud to combine the prescription system of Mayaud with the inventory system of Lester, as they are wholly unrelated functions." The arguments have been fully considered but are not found to be persuasive, because modifying Mayaud, by the teachings of Lester et al.'s computer software drug inventory management program would only improve the functionality of Mayaud's invention and not alter it. Also, modifying Mayaud, by the teachings of Lester et al. would assist a hospital's pharmacist or pharmacy department with maintaining accurate records while attempting to reduce the burden of managing all of the information associated with drug distribution (See Lester et al., column 1, lines 29-33), as stated in the office action mailed 6/14/2005.

Further, in response to applicants' arguments above, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a

reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mellissa M. Chojnacki whose telephone number is (571) 272-4076. The examiner can normally be reached on 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Rones can be reached on (571) 272-4085. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 30, 2005
Mmc

SAM RIMELL
PRIMARY EXAMINER